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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/529,106

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Morris J. Robins

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EXAMINER

LAU, JONATHAN S

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/529,106	Applicant(s) ROBINS ET AL.	
	Examiner Jonathan S. Lau	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8,10,12,14,16 and 18-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8,10,12,14,16 and 18-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Withdrawal of Finality

Finality of the Office Action mailed 09 July 2008 is withdrawn in view of new grounds of rejection under 35 U.S.C. 112. Applicant's Amendment, filed 09 Sep 2008, is entered as a matter of right.

This Office Action is responsive to Applicant's Amendment and Remarks, filed 09 Sep 2008, in which claims 1-7, 9, 11, 13, 15 and 17 are canceled, claims 8, 10, 12, 14, 16 and 18 are amended, and new claims 19-24 are added.

This application is the national stage entry of PCT/US03/30386, filed 25 Sept 2003, and claims benefit of US Provisional Application 60/413,915, filed 25 Sept 2002, and US Provisional Application 60/416,329, filed 04 Oct 2002.

Claims 8, 10, 12, 14, 16 and 18-24 are pending.

Rejections Withdrawn

Applicant's Amendment, filed 09 Sep 2008, with respect to claims 1, 2, 4 and 5 rejected under 35 U.S.C. 103(a) as being unpatentable over Chen (US Patent 5,208,327, of record) has been fully considered and is persuasive, as claims 1, 2, 4 and 5 are canceled.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 09 Sep 2008, with respect to claims 3 and 6 rejected under 35 U.S.C. 103(a) as being unpatentable over Chen (US Patent 5,208,327, of record) in view of Bauman et al. (US Patent 5,668,270, of record) has been fully considered and is persuasive, as claims 3 and 6 are canceled.

This rejection has been **withdrawn**.

The following are new grounds of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-24 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 19 recites "a protecting group" and "a 6-(substituted oxy) group having sufficient reactivity in an S_NAR replacement reaction". Claim 20 recites "a protecting group", "substituted alkyl" and "substituted aryl". Claim 21 recites "a protecting group", "substituted alkyl" and "substituted aryl". Claim 22 recites "a protecting group" and "a halogen compound". Claim 23 recites "a 6-leaving group having lesser reactivity than that of the 2-amino group in a diazotization/chloro-dediazoni-ation displacement reaction." Claim 24 recites "substituted alkyl" and "substituted aryl".

The specification discloses protecting groups, such as acyl, silyl, amide at paragraph 12 of the corresponding PGPub 2007/0032645 which meet the written description and enablement provisions of 35 USC 112, first paragraph. The specification discloses substituents, such as the substituted alkyl group fluoroalkyl at paragraph 15 of the corresponding PGPub which meet the written description and enablement provisions of 35 USC 112, first paragraph. The specification discloses halogen compounds, such as metal chlorides, metal chloride salts, acyl chlorides, sulfonyl chlorides, and silyl chlorides, alkyl and aryl substituted ammonium chloride salts, including but not limited to tetraalkyl and aryl ammonium chloride salts, disclosed in paragraph 20 of the corresponding PGPub which meet the written description and enablement provisions of 35 USC 112, first paragraph. The specification discloses “a 6-(substituted oxy) group having sufficient reactivity in an S_NAR replacement reaction” and “a 6-leaving group having lesser reactivity than that of the 2-amino group in a diazotization/chloro-dediazoniatio displacement reaction”, such as alkyl- or arylsulfonyl groups and chlorine at paragraph 14 of the corresponding PGPub which meet the written description and enablement provisions of 35 USC 112, first paragraph.

However, claims 19-24 are directed to encompass “a protecting group”, “a 6-(substituted oxy) group having sufficient reactivity in an S_NAR replacement reaction”, “substituted alkyl”, “substituted aryl”, “a halogen compound”, and “a 6-leaving group having lesser reactivity than that of the 2-amino group in a diazotization/chloro-dediazoniatio displacement reaction”, which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these functional groups and

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chemicals meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and because chemical functional groups and compounds are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim. The examples recited above are part of non-limiting exemplary definitions.

The recitation, “a 6-(substituted oxy) group having sufficient reactivity in an S_NAR replacement reaction” and “a 6-leaving group having lesser reactivity than that of the 2-amino group in a diazotization/chloro-dediazoniation displacement reaction”, is seen to be merely functional language.

Functional language at the point of novelty, as herein employed by Applicants, is admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC, 1997) at 1406: stating this usage does “little more than outline goal appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate”. The CAFC further clearly states that “[A] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials” at 1405(emphasis added), and that “It does not define any structural features commonly possessed by members of the genus that distinguish from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the

genus.." at 1406 (emphases added). The example recited above of said 6-(substituted oxy) group and said 6-leaving group are part of non-limiting exemplary definitions, and do not provide sufficient written description to support the genus of said 6-(substituted oxy) group and said 6-leaving group because chemical functionalities are highly variant and encompass a myriad of possibilities

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed derivatives, analogs, etc., regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

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...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only the structurally defined chemical compounds, but not the full breadth of the claims, meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See Vas-Cath at page 1115.)

The court of *In re Curtis* held that "a patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when... the evidence indicates ordinary artisans could not predict the operability ... of any other species." (see *In re Curtis* 354 F.3d 1347, 69 USPQ2d 1274, Fed. Cir. 2004). The court of *Noelle v. Lederman* also pointed out that generic claim to anti-CD40CR Mabs lacked written description support because there was no description of anti-human or other species Mabs, and no description of human CD40CR antigen. The court further pointed out that attempt to "define an unknown by its binding affinity to another unknown" failed. See 355 F.3d 1343, 69 USPQ2d 1508, Fed. Cir. 2004.

Claims 8, 10, 12, 14, 16 and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some temperatures less than 0°C, for example at -5 to 0°C at paragraph 37 of the corresponding PGPub, does not reasonably provide enablement for all temperatures less than 0°C. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: A method for producing 2-chloro-2'-deoxyadenosine.

The state of the prior art: Chen (US Patent 5,208,327, of record) discloses the replacement of the 2-amino group in 2-amino-6-chloropurine with a 2-chloro group in refluxing dichloromethane (column 7, Example 3 at lines 55-70).

It is well known in the art that no chemical reactions occur at absolute zero, -273.15 °C, because no molecular motion occurs at that temperature.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: While the reactivity of most chemical functionalities is relatively predictable, the sheer number of reaction conditions and concentrations means that one skilled in the art cannot predict the usefulness for all possible reaction temperatures. Therefore the claimed invention is unpredictable.

The Breadth of the claims: The scope of the claims is broad. Any temperature less than 0°C is encompassed by the claims. The claims encompass the temperature absolute zero, -273.15°C.

The amount of direction or guidance presented: The specification speaks generally about side products produced at prior art reactions at lower temperatures, such as the 6-oxopurine derivatives produced at -20 to 0°C at paragraph 16 of the corresponding PGPub. It is suggested that the reaction occurs at -5 to 0°C at paragraph 21 of the corresponding PGPub. However, guidance is not given for a lower limit for the temperature at which the reaction is envisioned.

The presence or absence of working examples: The only working examples provided are for the reaction at -5 to 0°C at paragraph 37 of the corresponding PGPub.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable art such as chemical synthesis. See MPEP 2164.

The quantity of experimentation necessary: In order to practice the invention with the full range of all possible temperatures beyond those known in the art, (such as reflux or -5 to 0°C) one skilled in the art would undertake a novel and extensive research program to establish the lower limit for the temperature at all reaction conditions. Because this research would have to be exhaustive, and because it would

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involve such a wide and unpredictable scope of synthetic reactions, it would constitute an undue and unpredictable experimental burden.

Genentech, 108 F.3d at 1366, states that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the breadth of the claims, Applicants fail to provide information sufficient to practice the claimed invention for all possible temperatures lower than 0°C.

Conclusion

No claim is found to be allowable.

This Office Action details new grounds of rejection not necessitated by Applicant's Amendment. Accordingly, this Office Action is Non-Final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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